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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--------------------------|-------------|-----------------------|---------------------|------------------|
| 09/913,345 | 03/25/2002 | Jan Gerrit Garsen | 5034US | 8607 |
| 7590 08/01/2006 | | | | |
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| Salt Lake City, UT 84110 | | | | |
| | | EXAMINER | | |
| | | SWARTZ, RODNEY P | | |
| | | ART UNIT PAPER NUMBER | | |
| | | 1645 | | |

DATE MAILED: 08/01/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/913,345

Applicant(s)

GARSSEN ET AL.

Examiner

Rodney P. Swartz, Ph.D.

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 May 2006.
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7, 11-16, 20 and 21 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 1-7, 11-16, 20, 21 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Applicants' Response to Office Action, received 5 May 2006, is acknowledged. Claims 1, 20, and 21 have been amended.
2. Claims 1-7, 11-16, 20, and 21 are pending and under consideration.

Rejections Withdrawn

3. The rejection of claim 20 under 35 U.S.C. 112, second paragraph, as being indefinite for the number of mammalian subjects, is withdrawn in light of the amendment of the claim.

Rejections Maintained

4. The rejection of claims 1-5, 11-13, and 15 and now new claim 21 under 35 U.S.C. 102(b) as being anticipated by Grathwohl et al (*Journal of Virological Methods*, 64:205-216, 1997) is maintained for reasons of record.

Applicants argue that Grathwohl et al does not teach each and every element as set forth in the newly amended claims, i.e., preparing a test set (treated with GdnSCN) and a control set (not treated with GdnSCN).

The examiner has considered applicants' argument, but does not find it persuasive. Page 208, section 2.4 ELISA, first paragraph, lines 7-13, state that both a GdnSCN and a SDS sample was prepared prior to application to ELISA plated. In addition, section 3.1, first paragraph, lines 3-9, indicate that Grathwohl et al do teach an assay with and without treatment with GdnSCN, i.e., a test and control sample. The results are shown in Figure 2.

5. The rejection of claims 6 and 7 under 35 U.S.C. 103(a) as being unpatentable over Grathwohl et al (*Journal of Virological Methods*, 64:205-216, 1997) is maintained for reasons of record.

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Applicants argue that because dependent claim 6 and 7 are dependent from nonobvious claim 1, they are nonobvious.

The examiner has considered applicants' argument, but does not find it persuasive because the rejection of independent claim 1 as being anticipated by Grathwohl et al is maintained.

6. The rejection of claim 14 under 35 U.S.C. 112, second paragraph, as being indefinite for dependence from a rejected claim, is maintained for reasons of record.

New Rejection Necessitated by Amendment

Claim Rejections - 35 USC § 112

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claim 20 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 20 depends from a rejected claim.

Conclusion

9. Claims 1-7, 11-16, 20, and 21 are finally rejected.

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of

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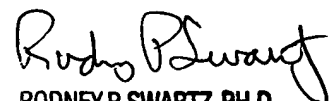
the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rodney P. Swartz, Ph.D., Art Unit 1645, whose telephone number is (571) 272-0865. The examiner can normally be reached on Monday through Thursday from 5:30 AM to 4:00 PM EST.

If attempts to reach the Examiner by telephone are unsuccessful, the examiner's supervisor, Lynette F. Smith, can be reached on (571)272-0864.

The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



RODNEY P SWARTZ, PH.D
PRIMARY EXAMINER

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July 22, 2006